Regulation of Perchlorate in Drinking Water

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Public Meeting and Webcast

September 20, 2012

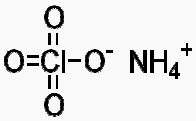
Presentation Overview

- Perchlorate background
- Perchlorate in drinking water regulatory history
- Safe Drinking Water Act (SDWA) requirements for the development of National Primary Drinking Water Regulations (NPDWR)
- Science Advisory Board (SAB) review
- Stakeholder involvement
- Next steps

What is Perchlorate?

- Perchlorate exists primarily as a salt.

  Most commonly used perchlorate salts include ammonium perchlorate and potassium perchlorate.



- Variety of industrial uses, it is primarily used in the form of ammonium perchlorate as an oxidizer in solid fuels to power rockets, missiles, and fireworks.
- Perchlorate also occurs naturally:
  - Calcium carbonate deposits of arid or semiarid regions (e.g., the High Plains of Western U.S.A.)
  - Atmospheric processes
- An impurity in disinfectant (hypochlorite) solutions

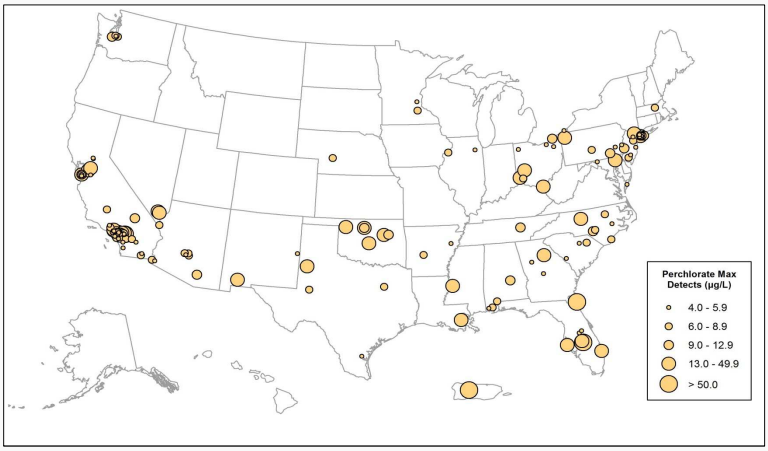
What are the Effects of Perchlorate?

- Perchlorate interferes with the thyroid gland by inhibiting iodide uptake.
- Reduced iodide uptake by the thyroid impacts the amount of thyroid hormones produced.
- Thyroid hormones are critical for normal growth and development.
- Poor iodide uptake and subsequent impairment of thyroid function in pregnant and lactating women are linked to delayed development and decreased learning capability in their infants and children.

How are People Exposed to Perchlorate?

- Food
  - Food and Drug Administration's Total Diet Study (2005 – 2006)
    - Detectable levels of perchlorate found in 74% (211 of 285) of foods
    - The range of average estimated perchlorate intakes was 0.08 to 0.39 µg/kg/day
  - Centers for Disease Control's infant formula study (2009)
    - Perchlorate found in all brands/types tested
- Drinking water
  - EPA's Unregulated Contaminant Monitoring Rule (2001 – 2005)
    - 4.1% of public water systems (160/3,865) reported at least 1 perchlorate detection
    - 2.3% to 7.3% of the population served by the sampled systems estimated to be exposed to perchlorate (5.1 M to 16.6 M people) from drinking water

System–Level Geographic Distribution of Perchlorate



Perchlorate in Drinking Water Regulatory History

- March 2, 1998, February 24, 2005, and October 8, 2009 EPA included perchlorate on the first, second, and third Contaminant Candidate Lists.
- October 10, 2008, EPA published a preliminary regulatory determination for perchlorate (73 FR 60262), requesting public comment on its determination that a NPDWR for perchlorate would not present a meaningful opportunity for health risk reduction for persons served by public water systems.
- August 19, 2009, EPA published the *Perchlorate Supplemental Request for Comments* (74 FR 41883) requested comment on additional approaches to analyzing data. EPA stated that the alternative analyses could lead the Agency to make a determination to regulate perchlorate.
- On February 11, 2011 (76 FR 7762), EPA announced its decision to regulate perchlorate based on its finding that perchlorate meets the SDWA's three criteria for regulating a contaminant.
  1. Perchlorate may have adverse health,
  2. There is a substantial likelihood that perchlorate occurs with frequency at levels of health concern in public water systems, and
  3. There is a meaningful opportunity to reduce risk through a drinking water regulation.

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SDWA Requirements for the Development of NPDWRs

- Once EPA makes a determination to regulate a contaminant in drinking water, Section 1412(b)(1)(A) requires that EPA issue a proposed NPDWR within 24 months and a final NPDWR within 18 months after the proposal (the statute allows a nine month extension of this promulgation date).
- Section 1412(a)(3) requires EPA to propose an MCLG simultaneously with the NPDWR.
  - The MCLG is "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."
  - Non enforceable public health goal
- Section 1412(b)(4)(B) states that the MCL will be set as close to the MCLG as is feasible.
  - "Feasible" means with the use of the best technology, treatment techniques and other means which the Administrator finds are available (taking cost into consideration)
  - EPA evaluates both treatment technologies and the analytical methods

SDWA Requirements for the Development of NPDWRs (continued)

- When proposing an MCL, EPA must publish, and seek comment on, the health risk reduction and cost analyses (HRRCA) of each alternative MCL considered (section 1412(b)(3)(C)(i)).
  - Estimates of the quantifiable and non-quantifiable health risk reduction benefits
  - Estimates of the quantifiable and non-quantifiable costs of compliance (monitoring treatment and other costs
  - Incremental costs and benefits of each alternative MCL considered
  - Effects of a contaminant on the general population, and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.
  - Any increased health risk that may occur as the result of compliance
  - Other relevant factors including quality and extent of information as well as uncertainties.

SDWA Requirements for the Development of NPDWRs (continued)

- Section 1412(b)(4)(E)(ii) requires EPA, when promulgating an NPDWR, to list technologies that achieve compliance with the MCL and are affordable for systems in three specific population size categories: 25-500, 501-3300, and 3301-10,000.

Science Advisory Board Review

- In accordance with section 1412(d) and (e), the Agency initiated SAB review on how to consider available scientific data in deriving an MCLG for perchlorate.
- Panel formation began in December of 2011
- EPA charged the SAB with providing input on four issue areas related to the development of a perchlorate MCLG:
  - How should EPA consider sensitive life stages?
  - How should EPA consider physiologically-based pharmacokinetic (PBPK) modeling?
  - How should EPA consider post-RfD epidemiology data?
  - How can EPA best use the total body of information?
- July 18-19, 2012: Advisory Panel meeting
- September 5, 2012: Draft "SAB Advisory Report on Approaches for Deriving an MCLG for Perchlorate"

Science Advisory Board Review (continued)

- SAB next steps:
  - Perchlorate Advisory Panel Teleconference to discuss draft report
  - Revise report for Panel consensus based on public teleconference
  - Chartered SAB QA review teleconference
  - Revise Quality Review Draft for Chartered SAB approval of Final Report
  - Final Report to the Administrator
- See "Public Involvement in Advisory Activities" http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument
- For further information contact the SAB DFO, Thomas Carpenter at 202-564-4885

Stakeholder Involvement

- Stakeholder involvement to date
  - March 2011 – stakeholder meeting for potential environmental justice communities
  - Tribal consultation and coordination: September 2011 – National Tribal Water Council; Tribes in December 2011; January 2012; February 2012; and May 2012
  - SAB Perchlorate Advisory Panel Public meeting – July 18 and 19

- Upcoming stakeholder involvement
  - Today's meeting – focus on treatment technologies and analytical methods
  - SAB Perchlorate Advisory Panel Teleconference – September 25, 2012
  - National Drinking Water Advisory Council – October 4, 2012
  - SAB Quality Assurance Review – TBD
  - Small entity representative input in accordance with the Small Business Regulatory Enforcement Fairness Act (SBREFA) – TBD
  - Notice of proposed rulemaking – SDWA deadline February, 2013